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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,592	08/19/2003	Christian Miculka	612,406-035	5273

7590 02/16/2006

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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,592	MICULKA ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Seq. ID Request*.

The application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §1.821 through §1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given **3 (THREE)** MONTHS from the date of this letter within which to comply with the sequence rules, 37 C.F.R. §1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. §1.821(g). Extension of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. §1.136. In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Applicant is requested to return a copy of the attached Notice To Comply with the response.

Applicant is referred to the combined nucleic acid/polypeptide sequences disclosed at page 62 at line 76 and page 63 at lines 16 and 22-28 of the specification.

No claims have been cancelled, claim **2** has been amended, the disclosure has been amended at page one thereof, and new claims **3-11** have been added as per the preliminary amendment filed August 30, 2004. One Information Disclosure Statement (1 IDS) filed August 30, 2004 has been received and made of record.

Claims **1-11** remain in the case.

The disclosure is objected to because of the following informalities:

At pages 1, 4 and 6 of the disclosure, formulas are provided which are inaccurate representations because each contains many valence errors. Applicant is referred to the structures at columns 1, 3 and 4 of the parent patent **6,608,186** (PTO-892 ref. **H**) for guidance concerning how this problem has been effectively addressed. See also the Abstract wherein the same error is also exemplified twice.

Molecular structures represented at pages 23, 31, 46, 47, 49, 50 and 53 are incompletely reproduced from the submitted pages. Applicant is respectfully requested to resubmit the

noted structural formulas with the lines darkened and the letters darkened, or otherwise amended, to insure that scanning of the substitute submissions will produce images that are entirely legible.

Appropriate correction is required.

Claims **1-11** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed exemplifications.

Claims **1 and 7** are characterized by several functional terms ("biomolecule conjugated through a covalently linkage," "pentopyranosyl subunits are covalently linked between carbon 4 and carbon 2 of their respective pentopyranosyl rings," and "the pentopyranosyl nucleic acid does not stably hybridize to naturally occurring DNA or RNA"), which functional terms have not been further defined by specific chemical structural formulas, and which therefore render the scope of the claims greatly in excess of the scope of the specific exemplifications. Without knowledge of the structural particulars implied by the instant functional terms, the instant claims fail to provide the minimum guidance required by the ordinary practitioner to know the particular identities of the claimed "compounds." Examiner suggests substantial narrowing of the instant claims scopes to more nearly correspond to the scope of the instant disclosed embodiments by introduction of chemical structures which define the pentopyranosyl nucleic acids, the linking moieties, and all other structural features the identities and scopes of which the instant terminology fails to define. Examiner also notes that the instant claims, while directed to nucleotide analog-derived oligomers, fail to provide sufficiently detailed guidance concerning all of the particular functional groups encompassed by the instant claims. And while examiner has no reason to question the limitation "does not stably hybridize to naturally occurring DNA or RNA," it is likely that other nucleic-acid-like oligomers will also self associate (self hybridize) while not hybridizing with naturally occurring RNA or DNA, but applicant has not provided sufficient guidance to permit the ordinarily skilled to know how to use all of the species within the scope of the instant claims (hybridization behavior not provided for all alternative structures). In light of the very limited scope of applicant's disclosed specific embodiments which only provide guidance concerning a very limited number of pentopyranosyl nucleic acid 8mers and only a few non-"biotin" oligopeptide

conjugates thereof, appropriate clarifying and narrowing amendments are respectfully requested.

Claims **1-11** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** at lines 2, 3 and 5, the terms "at least one" and "at least two" are indefinite because each term fails to define an upper bound of the claimed subject matter. See also claim **2** at line 2 wherein the term "one or more" has the same problem. See also claims **4, 5 and 6** also include one of the noted terms.

In claim **1** at line 3 the term "biomolecule" renders the instant claim indefinite because said term has not been further defined within the instant claim and therefore the instant claim lacks well defined metes and bounds. In addition the structure of the claim wherein the terms "biomolecule" and "pentopyranosyl nucleic acid" and asserted to be part of a "compound" is incorrect because "[a] compound" is not a mixture of other compounds.

In claim **1** at line 3 the term "biomolecule conjugated through a covalent linkage" is incomplete because the noted term fails to define a particular chemical functional group or groups which are doing the "linking." See also this claim at lines 6-7 wherein the term "pentopyranosyl subunits are covalently linked between carbon 4 and carbon 2 of their respective pentopyranosyl rings" has the same problem. See also claim **2** at lines 3-4 wherein the term "each moiety is conjugated to either the biomolecule or the pentopyranosyl through a covalent linkage" is indefinite for the same reason. See also claim **8** at lines 2-3 wherein the same error reoccurs.

In claim **1** at lines 7-8, the term "does not stably hybridize to naturally occurring RNA and DNA" is an improper negative limitation, which limitation fails to "particularly point out and distinctly claim the subject matter which applicant regards as the invention."

In claims **1 and 7** the term "comprising" is incorrect in a compound claim because said term implies that the claim fails to completely define the compound being claimed; e.g. said term suggests that additional structural components are present ("included") in the

"compound" but are not defined by the claim. Examiner suggests substitution of the term -- consisting of -- for the noted term.

In claim **2** at lines 2-3 the terms "detectably labeled moiety" and "moiety for attachment to a solid support" are indefinite for failure to define either the location(s) of attachment(s) or the particular identities of the moieties encompassed by the noted functional terms.

In claim **3** the Markush group incorrectly implies multiple valence errors and should be amended to read "selected from the group consisting of a DNA molecule, an RNA molecule, a peptide, a protein, an antibody, and a functional antibody fragment."

In claim **4** the term "biomolecule is linked ... through a phosphate linker" is incomplete because the structure of the "phosphate linker" has not been completely defined and because the locations of attachment have also not been completely defined.

In claim **5** the term "biomolecule is linked ... through a base of a pentopyranosyl nucleotide subunit" is incomplete because the structure of the chemical identity of the implied "linker" has not been defined, and because the locations of attachment on the various different "bases" have also not been completely defined.

In claim **7** the term "biotin molecule" is incorrect because in fact a radical derived from "biotin" will be a substituent in the molecule defined by the claim, not a separate species as suggested by the term "molecule."

In claim **7** the term "conjugated to the biotin molecule" is incomplete because the locations of conjugation or the particular "linker" present to achieve said conjugation have not been defined in the claim. See also claims **9-11** wherein the same error is also present because in each claim the particular "linker" containing a "phosphate," "an amide," or other linker having the capability of forming "a covalent linkage" have not been completely defined.

In claim **9** the term "phosphate bond" is unclear because said term suggests that said "bond" may be either a -- phosphate ester -- bond, or a -- phosphoric acid anhydride -- bond, two very different alternatives. Clarification is respectfully requested.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy

reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-11** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-5*** of U. S. Patent No. **6,608,186** (PTO-892 ref. **H**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and the patented compound claims are directed to substantially overlapping subject matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims **1-6** are rejected under 35 U.S.C. §102(**a**) as being anticipated by **Hoechst '943** (PTO-892 ref. **O**).

Applicant is referred to the **'943** reference abstract and claims wherein the instant claimed subject matter is anticipated. In particular see claim ***8*** wherein variations in the covalent linkages between pentopyranosyl nucleoside units have been specified. In particular

note claim *12* wherein a pentopyranosyl nucleic acid is optionally derivatized by peptides and/or by fluorescent markers. See also Figure 1 wherein a pentopyranosyl nucleic acid has been derivatized by the attachment of amino acid substituents.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

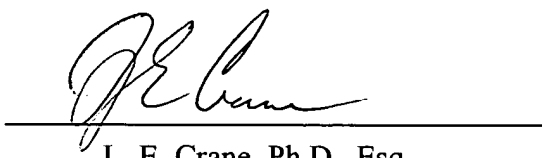
Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
10/25/2005



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